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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

Phillip D. Purdy

Serial No.: 09/905,670

Filed: July 13, 2001

For: Methods and Apparatuses for Navigating the  
Subarachnoid Space

Group Art Unit: 3767

Examiner: MACNEILL, ELIZABETH

Atty. Dkt. No.: UTSD:798US

**37 C.F.R. § 1.132 DECLARATION OF PHILLIP D. PURDY**

I, Phillip D. Purdy, declare:

1. I am one of the inventors of this application.
2. I am a professor at UT Southwestern Medical School. My primary appointment is in Radiology and I have a secondary appointment in Neurological Surgery. I received a Bachelor of Science degree in psychology from Southern Methodist University in 1974, and a Doctor of Medicine from the University of Missouri in 1978. I completed a residency in Neurology at UT Southwestern from 1979-1982 and a residency in Diagnostic Radiology at UT Southwestern from 1982-1985.
3. I have a financial interest in the outcome of this patent application.
4. I participated in a telephone interview with the Examiner on October 2, 2007. The Examiner questioned whether it was possible to navigate from the spinal subarachnoid space after entry near the base of the skull into the intracranial subarachnoid space. I explained that it was not due to the severe risk of injury involved. The limitation in development of medical procedures relating to navigation into the intracranial subarachnoid space from a cervical insertion has been that the spinal cord occupies the subarachnoid space throughout the cervical

spine. The only approach that has been developed to that space has been posteriorly between the first and second cervical vertebrae, where there is a small space approximately 2-3 mm in width separating the spinal cord from the posterior margin of the spinal subarachnoid space. To approach that space, one must insert a needle perpendicularly from a lateral approach. This is the approach that is used for cervical myelography and for withdrawal of CSF using a “cervical puncture” technique, and I have used that approach many times in my practice. However, in order to then navigate the subarachnoid space from that approach, it would be necessary to make an abrupt 90-degree turn either cephalad or caudad within the canal, and in order to navigate to the more significant structures in the posterior fossa (the cranial nerves, arteries, and brainstem), one would have to encircle the spinal cord while making that 90-degree turn. The mechanics of this move are such that extreme risk of injury to the spinal cord, blood vessels, or lower cranial nerves would ensue. Hence, this approach would be unworkable from a patient risk standpoint.

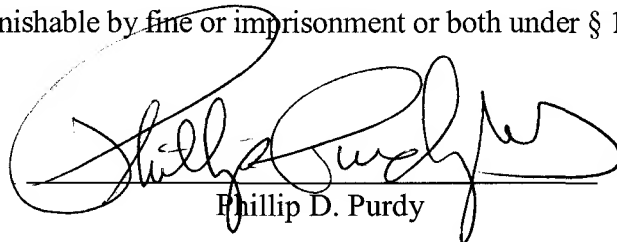
5. The Examiner suggested during the telephone interview that US 4,904,237 (Janese) might be relevant to the claims in this patent application in terms of intracranial access. I have reviewed the Janese patent, and find no discussion or suggestion of advancement from the spinal subarachnoid space into the intracranial subarachnoid space. The focus of the patent is the computerized fluid exchange apparatus. Janese explains that the apparatus can be used to remove CSF through a catheter inserted in the subarachnoid space; the apparatus then treats and returns the CSF to the subarachnoid space. Janese states that the apparatus “provides prophylaxis against symptomatic intra-cranial arterial spasm by removing blood and blood byproducts from the cerebrospinal fluid and by cooling the circulated cerebrospinal fluid and by cooling the circulating cerebrospinal fluid to improve injured brain survival.” Col. 2. Janese also states that his apparatus can be used to treat intracranial arterial vasospasm, brain trauma,

and fetal intracranial hemorrhage. Col. 10. However, nothing in the patent discusses or suggests navigation into the intracranial subarachnoid space to accomplish any of those suggested treatments. For example, Janese does not provide any information about monitoring the location of the catheter within the subarachnoid space. Additionally, Janese describes allowing a patient to rest on her side after the catheter is placed, which indicates that Janese does not contemplate or suggest intracranial navigation. A patient undergoing such navigation would be much more likely to be prone during that procedure.

6. The Examiner also suggested that US 6,379,331 (Barbut) might be relevant to the claims in this patent application. Barbut illustrates an embodiment in which the catheter is inserted at the C6-C7 interspace. However, there is no safe insertion point for a catheter at C6-C7 because the spinal cord is immediately adjacent to the dura at that location. In fact, the spinal cord actually widens in the lower cervical spine to occupy more of the subarachnoid space due to the extensive innervation to the upper extremities that exit at that location. Furthermore, Barbut discloses cranial access for CSF exchange through a burr hole in the skull, which shows Barbut did not consider it reasonable to navigate from the spinal subarachnoid space into the intracranial subarachnoid space.

7. All statements made of my own knowledge are true and all statements made on information are believed to be true, and statements in this document were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code.

11-16-07  
Date

  
Phillip D. Purdy